UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

KEVIN PHILLIPS, Plaintiff, vs. C.R. BARD, INC. et al., Defendants.	3:12-cv-00344-RCJ-WGC **ORDER**

This case arises out of an allegedly defective surgically implanted medical device. Pending before the Court are twenty-five motions in limine, a motion to bifurcate trial, and a motion to seal.

I. FACTS AND PROCEDURAL HISTORY

The inferior vena cava ("IVC") is a vein that returns blood to the heart from the lower body. (Compl. ¶ 15, ECF No. 1-1). An IVC filter is a medical device residing in the IVC that catches blood clots or "thrombi" that travel from the lower portions of the body towards the heart and lungs, where they can cause serious injury or death. (*Id.* ¶¶ 14–16). IVC filters have been on the market since the 1960s. (*Id.* ¶¶ 13, 18). The first IVC filters were "permanent" filters, i.e., designed to remain in the patient for the patient's life. (*Id.* ¶ 18). In 2003, manufacturers began

producing "optional" or "retrievable" IVC filters that can be removed from a patient once the risk of a blood clot has subsided. (*Id.*). At issue in the present case is the Recovery Filter System ("RFS"). Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (C.R. Bard's subsidiary) "designed, set specifications [for], manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery Filter System and G2 Filter System ("G2FS") to be implanted in patients . . . ." (*Id.* ¶¶ 3–4). Although Plaintiff makes general allegations concerning the G2FS, as well as the RFS, he alleges only having had a defective RFS implanted in him. (*See id.* ¶¶ 49–51).

Due to manufacturing and design defects, the RFS has a high fracture and migration rate as compared to other IVC filters, and these defects can cause serious injury or death. (*See id.* ¶¶ 25–30). Defendants failed to conduct clinical testing such as animal studies on the RFS, and even after they became aware of large numbers of adverse event reports ("AER") from health care providers reporting serious injury or death due to the migration of the entire device or fractured pieces of the device, they failed to recall the RFS or even warn those who had been implanted with one, although they withdrew the RFS from the market. (*See id.* ¶¶ 31–35, 43–48). Plaintiff makes similar allegations concerning the G2FS, but again, he does not allege having been implanted with a G2FS. (*See id.* ¶¶ 36–42).

Plaintiff was implanted with Defendants' RFS on August 4, 2005. (*Id.* ¶¶ 49–50). The RFS subsequently failed and migrated to Plaintiff's heart, perforating his heart and causing severe and life-threatening complications requiring emergency open-heart surgery on April 30, 2010, and resulting in various economic and non-economic damages. (*Id.* ¶ 51). Plaintiff sued

Defendants in state court for: (1) negligence; (2) strict products liability—failure to warn; (3) strict products liability—design defects; (4) strict products liability—manufacturing defects; (5) breach of the implied warranty of merchantability; (6) negligent misrepresentation; and (7) violation of the Deceptive Trade Practices Act ("DTPA"), Nevada Revised Statutes §§ 598.0915(5), (15), 598.0923(2), and 598.0925(1)(a). Defendants removed, demanded a jury trial, and answered. Defendants filed four motions in limine and a motion for summary judgment. The Court denied the motions in limine and granted the motion for summary judgment in part. Plaintiff has now filed sixteen motions in limine, and Defendants have filed eight.

II. LEGAL STANDARDS

A motion in limine is a procedural device to obtain an early and preliminary ruling on the admissibility of evidence. Black's Law Dictionary defines it as "[a] pretrial request that certain inadmissible evidence not be referred to or offered at trial. Typically, a party makes this motion when it believes that mere mention of the evidence during trial would be highly prejudicial and could not be remedied by an instruction to disregard." Black's Law Dictionary 1171 (10th ed. 2014). Although the Federal Rules of Evidence do not explicitly authorize a motion in limine, the Supreme Court has held that trial judges are authorized to rule on motions in limine pursuant to their authority to manage trials. *See Luce v. United States*, 469 U.S. 38, 41 n.4 (1984) (citing Fed. R. Evid. 103(c) (providing that trial should be conducted so as to "prevent inadmissible evidence from being suggested to the jury by any means")).

Judges have broad discretion when ruling on motions in limine. *See Jenkins v. Chrysler Motors Corp.*, 316 F.3d 663, 664 (7th Cir. 2002). However, a motion in limine should not be used to resolve factual disputes or weigh evidence. *See C&E Servs., Inc., v. Ashland, Inc.*, 539 F. Supp. 2d 316, 323 (D.D.C. 2008). To exclude evidence on a motion in limine "the evidence must be inadmissible on all potential grounds." *E.g.*, *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004). "Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Hawthorne Partners v. AT&T Tech., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993). This is because although rulings on motions in limine may save "time, costs, effort and preparation, a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1219 (D. Kan. 2007).

In limine rulings are preliminary and therefore "are not binding on the trial judge [who] may always change his mind during the course of a trial." *Ohler v. United States*, 529 U.S. 753, 758 n.3 (2000); *accord Luce*, 469 U.S. at 41 (noting that in limine rulings are always subject to change, especially if the evidence unfolds in an unanticipated manner). "Denial of a motion in limine does not necessarily mean that all evidence contemplated by the motion will be admitted to trial. Denial merely means that without the context of trial, the court is unable to determine whether the evidence in question should be excluded." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

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III. ANALYSIS

A. Plaintiff's Motions in Limine

1. Motion No. 195

Plaintiff asks the Court to exclude references to his counsel's practices, advertisements, or fees. The Court grants the motion in part. *See* Fed. R. Evid. 401, 402. Defendants object only that it should be permissible for counsel to ask jurors during voir dire whether they have seen advertisements about IVC filter litigation. Without yet deciding whether the Court will permit this question during voir dire, the Court will not categorically exclude it at this time.

2. Motion No. 196

Plaintiff asks the Court to exclude reference to IVC filters as the "gold standard" of treatment for the relevant medical problems. The Court denies the motion. If Defendants have competent expert evidence that IVC filters are the preferred method of treatment, the expert may adduce the evidence as background information.

3. Motion No. 197/198[1]

Plaintiff asks the Court to exclude reference to surgical consent forms. The Court denies the motion because it cannot tell whether such evidence will be relevant without the context of trial. It is possible that consent forms may contain warnings relevant to the duty to warn or comparative fault.

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1 Some motions have been filed in both sealed and unsealed versions.

4. Motion No. 199

Plaintiff asks the Court to exclude references to collateral sources of payment for Plaintiff's medical bills. The Court grants the motion. *See McConnell v. Wal-Mart Stores, Inc.*, 995 F. Supp. 2d 1164, 1169–73 & nn.1–3 (D. Nev. 2014) (Jones, J.). Defendants respond that they do not intend to offer such evidence, unless Plaintiff "opens the door" and makes such evidence relevant.

5. Motion No. 200

Plaintiff asks the Court to exclude references to a "litigation crisis," or the potential impact of a verdict in Plaintiff's favor on the medical industry, the economy, or jurors themselves. The Court grants the motion. *See* Fed. R. Evid. 401, 402. Defendants respond that they do not intend to offer such evidence, unless Plaintiff "opens the door" and makes such evidence relevant.

6. Motion No. 201

Plaintiff asks the Court to exclude references to the previous exclusion of Plaintiff's expert witnesses in other cases. The Court denies the motion. The Court cannot say without the context of trial that such commentary or questions would be irrelevant or otherwise inadmissible in all cases. For example, such evidence may be relevant as impeachment of an expert's claim of his or her qualifications made in front of the jury.

7. Motion No. 202/203

Plaintiff asks the Court to exclude reference to FDA approvals of the device at issue of lack of any enforcement activities by the FDA against Defendants based on the device. The

Court denies the motion. Such evidence is relevant to show whether industry standards have been complied with, which is relevant to whether Defendants were negligent.

8. Motion No. 204

Plaintiff asks the Court to exclude reference to failure rates, complication rates, percentages, or comparative analysis of injuries different from those asserted in this case. The Court denies the motion. The Court cannot say this kind of evidence would be irrelevant. The overall rate of injury for the device at issue is relevant to whether Defendants exercised due care. For example, a jury could rationally reason that a defendant is not negligent for distributing a device that has an overall injury rate of 0.1% if other similar devices have similar injury rates, even if the rates of a particular kind of injury are higher for the defendant's device. That is, perhaps the device at issue had a higher injury rate for some kinds of injuries but a lower rate for other kinds of injuries, but the overall rate of injury was comparable. Certain kinds of injuries might also be more likely to cause more serious harm. This is a complex determination relating to whether Defendants were negligent that the Court will not take from the jury on a motion in limine.

9. Motion No. 205

Plaintiff asks the Court to exclude argument or evidence relating to the fault of non-parties. The Court grants them motion in part. It is true that the jury may only apportion fault as between parties to the case. *See* Nev. Rev. Stat. § 41.141(2)(b)(2). Defendants respond that the statute does not prevent them from arguing "that non-parties" were negligent and are responsible to some degree." Neither Plaintiff nor Defendants are completely correct. A jury may not

apportion fault to non-parties, and evidence or argumentation directed to showing non-parties' *comparative* fault is therefore inadmissible, but "[n]othing in NRS 41.141 prohibits a party defendant from attempting to establish that either no negligence occurred or that the *entire* responsibility for a plaintiff's injuries rests with nonparties . . . ." *Banks v. Sunrise Hosp.*, 102 P.3d 52, 67 (Nev. 2004) (emphasis added). That is, Defendants may argue that non-parties were *entirely* at fault and that Defendants were not at fault at all, and they may adduce otherwise admissible evidence in support. But they may not argue that non-parties are *partially* at fault or adduce evidence tending only to show comparative fault.

10. Motion No. 206/207

Plaintiff asks the Court to exclude evidence that IVC filters are "lifesaving devices." The Court denies the motion. Defendants may adduce testimony that this is true if they have it. Plaintiff also asks the Court to exclude statistics concerning thrombi and pulmonary embolisms in the general population. The Court cannot say that this would be irrelevant as background information.

11. Motion No. 208/209

Plaintiff asks the Court to exclude arguments that Defendants could not affix warning labels, given the physician additional warnings, or have enacted a recall without FDA approval. The Court denies the motion. Evidence of FDA requirements in changing warnings or the feasibility of having a particular warning changed by a particular date is relevant to whether Defendants were negligent in not changing warnings.

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12. Motion No. 219/220

Plaintiff asks the Court to exclude certain opinions of Dr. David Feigal, to wit: (1) that an epidemiological analysis determined there is no reliable evidence the IVF filter posed a greater risk of harm than other devices; (2) that complaint data cannot be used to make safety assessments or comparisons regarding medical devices; and (3) that there are "stimulated reporting" factors that could theoretically explain the higher reported failure rates for the IVF filter at issue. Plaintiff first argues that Dr. Feigal failed to apply reliable principles to sufficient facts or data as to the epidemiological analysis. The Court rejects this argument. The quoted segment of the deposition does not show that Dr. Feigal did not use reliable methods. It shows that Plaintiff's attorney and Dr. Feigal disagreed about how closely he had followed Dr. Feigal's own previously stated definition of an epidemiological analysis. Dr. Feigal's failure (if it can be called that) to include certain of Defendants' data in his analysis does not necessarily render his methods invalid or the data he used unreliable. Plaintiff may impeach Dr. Feigal by pointing out (if it is true) that there was certain relevant evidence available to him that he did not consider.

Next, Dr. Feigal's opinion that complaint data cannot be used to make safety assessments or comparisons of devices is not the kind of expert opinion amenable to a proper methods–sufficient data examination because the opinion is not the result of a scientific test. It is an opinion about what methods are appropriate in making a certain kind of assessment. Plaintiff may counter this opinion with that of his own expert or challenge Dr. Feigal's reasoning on cross-examination. The same is true of Dr. Feigal's opinion that there are "stimulated reporting" factors that could explain the higher reported failure rates for the IVF filter at issue. Plaintiff

argues that Dr. Feigal has no support, apart from speculation, that any stimulated reporting phenomena occurred in this case. If that is true, the testimony may be inadmissible for a lack of foundation, but the Court cannot categorically exclude it at this time.

13. Motion No. 221/222

Plaintiff asks the Court to exclude the testimony of Dr. Tsuda, who is expected to testify only that Plaintiff's physician did not breach his own duty of care when he implanted the device. The Court denies the motion. It is not yet clear whether Plaintiff will argue at trial that An IVF filter should not have been used in his case.

14. Motion No. 223/224

Plaintiff asks the Court to exclude testimony that the IVC filter was misplaced or could not be expected to perform as it was placed. The Court denies the motion. This kind of testimony would plainly be relevant to causation, i.e., whether any defect was a cause of the harm. Defendants must have competent evidence to this effect, but the Court cannot categorically exclude it.

15. Motion No. 225/226

Plaintiff asks the Court to exclude testimony that Plaintiff did not take his anti-coagulant medication as prescribed, and that if he had, he would not have developed clots. The Court denies the motion. Again, Defendants must have competent evidence of Plaintiff's failure to take his prescribed medication, and any expert as to the likelihood of not developing clots if the medication had been taken must be admitted both as to his qualifications and his methods, but

the Court cannot categorically exclude this kind of evidence, which is plainly relevant to causation and comparative fault.

16. Motion No. 227/228

Plaintiff asks the Court to exclude evidence of the Society of Interventional Radiology ("SIR") Guidelines to show acceptable rates of complications. The Court denies the motion. Defendants will have to adduce a qualified expert as to the use of these guidelines in the industry to evaluate safety and that the guidelines at issue should apply to the device at issue, but if they can do so, industry standards are relevant to the negligence question.

B. Defendants' Motions in Limine

1. Motion No. 211

Defendants ask the Court to exclude evidence of other incidents of IVC failure if not sufficiently similar to the alleged failure in this case. The Court denies the motion. Failures of any kind causing injury occurring before the incident here are relevant to Defendants' knowledge of the risk of harm to Plaintiff and thus to whether they exercised due care. The evidence would not be admissible to show causation, however, and Defendants might be entitled to a limiting instruction.

2. Motion No. 212

Defendants ask the Court to exclude evidence of comparative failure rates of their IVC filter and other manufacturers' IVC filters. The Court denies the motion. The Court must consider the basis of any such testimony in the context of trial. Knowledge of a higher failure rate than those of competitors may be relevant to the negligence issue.

3. Motion No. 213

Defendants ask the Court to exclude evidence that Defendants withheld evidence from the FDA. The Court denies the motion. If Plaintiff has such evidence, it is as relevant as the FDA's approvals. The parties must argue to the jury what this evidence means. Plaintiff may not argue that the FDA would not have approved the device had it had full disclosure and certainly may not bring a state law fraud claim based on such an argument. Those issues and claims are preempted. But the issue is still relevant to Defendants' state of mind, i.e., to their knowledge of the risk, which is relevant to the negligence question. To rule otherwise would be to establish a "ceiling of care" based on FDA approval.

4. Motion No. 214

Defendants ask the Court to exclude evidence of C.R. Bard's criminal conviction in 1994 based on conduct in the 1980s. The Court agrees that the evidence would be much more prejudicial than probative, unless Plaintiff intends to use the fact to impeach a witness in the present case who was personally responsible for the previous criminal activity at C.R. Bard. That does not appear to be the case. Plaintiff responds that the evidence is admissible under Rule 404(b) as tending to show a "habit or custom" of Defendants. But that rule does not concern habits or customs, only "motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake." Fed. R. Evid. 404(b). It is Rule 406 that concerns habit-type evidence, and there is no claim that Defendants have a "habit" of violating the law in some particular way relevant to this case. In any case, Rule 406 cannot be used to circumvent Rule 404 if it does not relate to some narrowly concrete habit of behavior, and one previous incident of a particular

behavior is insufficient to show a habit. *Scott v. ABC*, 878 F.2d 386 (9th Cir. 1989) ("Rule 406 may be invoked only where a high degree of specificity and frequency of uniform response is present.").

5. Motion No. 215

Defendants ask the Court to exclude argumentation of a financial motive for downplaying the risks of the device. The Court denies the motion. Such a motive, if it can be shown, and not merely speculated upon, is at least relevant to punitive damages.

6. Motion No. 216

Defendants ask the Court to exclude evidence of state of mind, intent, motive, or ethics. The Court denies the motion. It targets too broad an area for the Court to make a categorical exclusion without the context of a particularized objection at trial.

7. Motion No. 217

Defendants ask the Court to exclude arguments that Defendants had an independent duty to conduct additional testing or that liability can result merely from a failure to do so. The Court grants the motion in part. Evidence of testing, and whether any additional testing was performed based on knowledge of certain defects or rates of failure, is relevant to whether Defendants exercised due care. There is, however, no independent duty to test, and liability cannot be based purely on a failure to conduct certain kinds of tests. Plaintiff has correctly identified the distinction in response.

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8. Motion No. 218

Defendants ask the Court to exclude evidence of their financial condition during the liability phase. The Court grants the motion. *See* Nev. Rev. Stat. § 42.005(4). The Court for the same reason grants the motion to bifurcate the trial into liability and punitive damages phases. Of course, as Plaintiff notes in response, such evidence may become admissible to rebut testimony adduced on behalf of Defendants that certain tests or designs were economically unfeasible.

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CONCLUSION

IT IS HEREBY ORDERED that the Motions in Limine (ECF Nos. 199, 200, 214, 218), the Motion to Bifurcate Trial (ECF No. 243), and the Motion to Seal (ECF No. 244) are GRANTED.

IT IS FURTHER ORDERED that the Motions in Limine (ECF Nos. 195, 205, 217) are GRANTED IN PART and DENIED IN PART.

IT IS FURTHER ORDERED that the Motions in Limine (ECF Nos. 196, 197, 198, 201, 202, 203, 204, 206, 207, 208, 209, 211, 212, 213, 215, 216, , 219, 220, 221, 222, 223, 224, 225, 226, 227, 228) are DENIED.

IT IS FURTHER ORDERED that the Motion in Limine (ECF Nos. 261, 262) is STRICKEN as untimely. *See* Local R. 16-3(b).

IT IS SO ORDERED.

Dated this 20th day of January, 2015.

ROBERT C. JONES
United States District Judge